VI. THE DATA MANAGEMENT SYSTEM

The Data Management System is the computer database that manages all project activities. It is divided into two main components: (1) the Clinic System, which tracks the recruitment and follow up activities conducted by the Pregnancy Advisors and Pregnancy Advisor Assistants in the prenatal care clinics; and (2) the Evaluation System, which tracks and manages the status of all telephone interviews. Information from these two Systems will be combined to manage data collection for Project HOPE.

It will be your responsibility to enter all of the data related to the telephone interviews onto the desktop computer in the Evaluation Office, which houses the Evaluation System. These data will allow the System to generate the reports necessary to schedule each interview, to conduct each interview, and to document each interview. This chapter describes the capabilities and components of the Evaluation System and provides instruction for its use.

A. Important Concepts

1. Result Codes and Ranges

The Evaluation System keeps track of the results of numerous events for each participant, such as her gestational age, eligibility for various interviews, and the result of every interview. It uses result codes to describe the status of each of these events, many of which you will be entering into the System. The result codes for the telephone interviews are exactly the same as those that you record in the Evaluation Contact Booklet, as described in Chapter IV. In addition, you will likely be entering codes that reflect the fact that a woman's pregnancy has ended, or perhaps that she has terminated her participation in the Project. When you apply a result code to a participant's record in the DMS, it is called *posting* a result code.

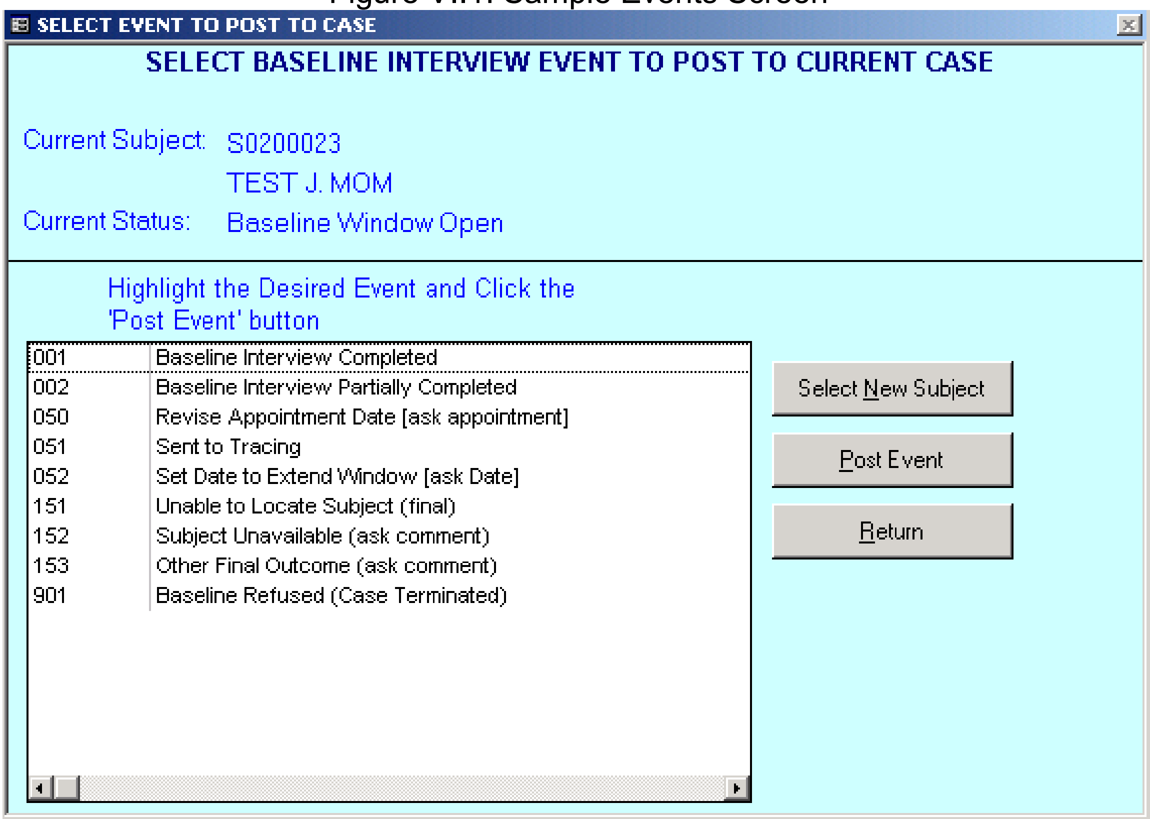
Since the System will keep track of numerous events, result codes are organized into groups called *ranges*. Each range is used to track a different event or activity of a participant's record. The most recent event posted into each range is stored in the master record for each participant. The event codes in the same range all begin with the same character prefix. For example, the event PREG01 is used to indicate the status of the subject currently being pregnant and PREG02 indicates a live birth. The set of ranges in the DMS that you will use is described in the Exhibit VI.1:

Exhibit VI.1: Range Event Prefixes in the Evaluation System

Range Description	Range Event Prefix
Pregnancy Status	PREG
Case Termination Events	TERM
Performance of Baseline Interview	BP
Performance of 22-26 Wk Follow-up	F1P
Performance of 34-38 Wk Follow-up	F2P
Performance of 6-10 Wk Postpartum	PFP

As shown in the table, the prefix is different for each range. However, for interview results, the last three digits of each result code are the same across the evaluations (these result codes are described in Chapter IV). When you select a result code for a participant in the DMS, you will see only the last three digits. The tracking system adds the prefix for you. For example, the suffix of the *Interview Completed* code is always 001, but the entire code for the baseline interview is BP0001 and for the first follow-up is F1P001 (the prefixes stand for Baseline Performance and Follow-up 1 Performance). Note that you don't have to remember the event codes. At any time that you are required to choose a code to post, you pick it from a list like that in Figure VI.1 below.

Figure VI.1: Sample Events Screen

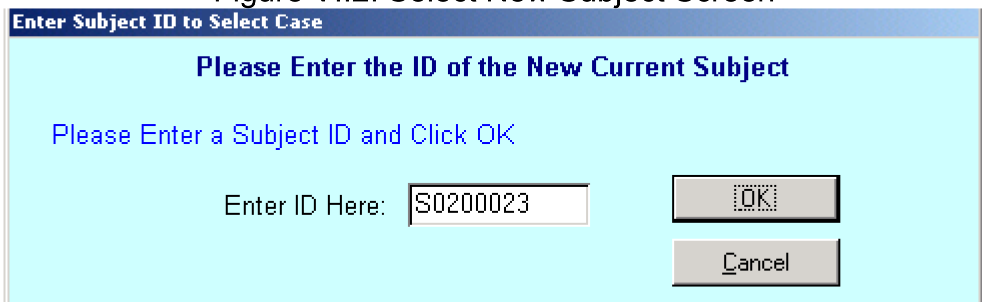


2. The Concept of a Current Case

In the Evaluation System, it is necessary to indicate the Subject ID number of the participant that you are working with BEFORE you perform an action on or enter any data for that participant. The Subject that you indicate remains the *current case* until you select a new participant, post and event to that participant's record, or attempt to enter an area where that participant is not allowed (because, as described in Chapter IV, the interview "window of time" is not open).

You always set a *current case* by clicking the *Select New Subject* button. This button will appear on almost every screen used to post activity results. When you do, the following window will appear:

Figure VI.2: Select New Subject Screen

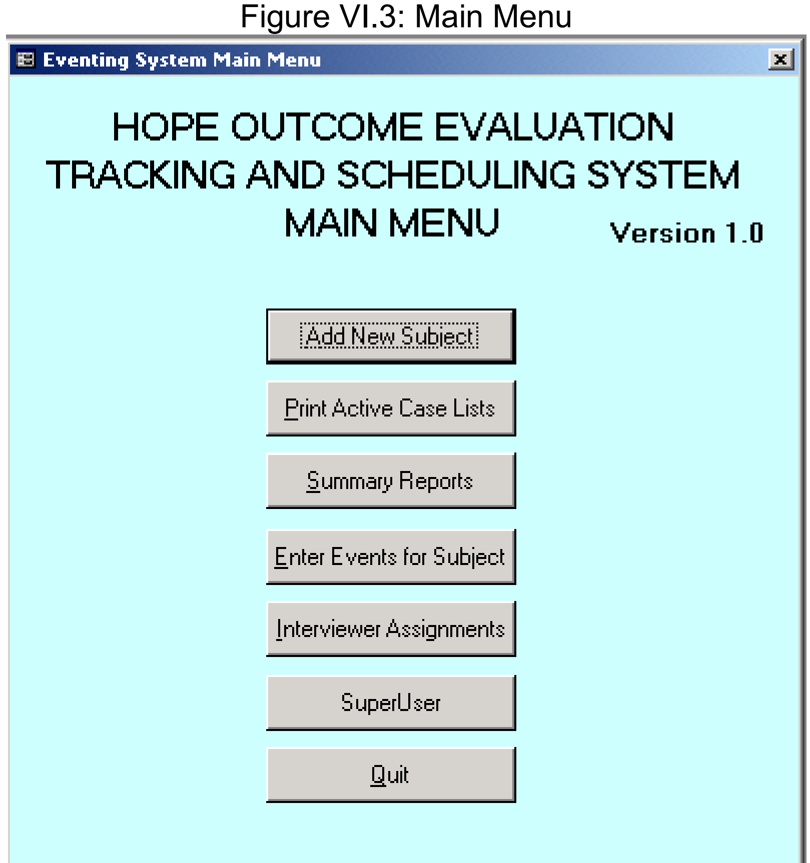


The Subject ID begins with an S has 8 digits. It is NOT necessary for you to enter the "S," as the entry system will add that for you. The last digit of the numeric portion of the ID is a code that is used to determine whether the ID has been entered correctly. Once you have entered all of the digits of a valid ID, the ID will be checked and the cursor will automatically move to the *OK* button. You may click the *OK* button to continue, or press the ENTER key.

B. The Main Menu

The Main Menu of the Evaluation System will always be the starting point for your data entry, as it displays all of the major functions of the system. Figure VI.3 shows what the Main Menu looks like:

Figure VI.3: Main Menu



The functions of the buttons on the main menu are as follows:

1. The *Add New Subject* button is used in Version 1.0 to add new subjects to the system. In Version 2.0, this function will be performed automatically using the clinic information that will be transmitted via telephone to the computer at the Evaluation Office. Until Version 2.0 is ready, the information to start a new case will have to be keyed via the Face Sheet, as described in Section C.

2. The *Print Active Case Lists* button is used to create a printout of the subjects that are currently scheduled for any of the four evaluations. This option is executed once a day, in the morning, to obtain from the system the telephone work for today. It is described further in Section D of this chapter.

3. The *Summary Reports* button is used to display a list of reports that can be printed to help track the progress of the study. These reports are described in Section E.

4. The *Enter Events for Subject* button displays a series of sub-menus that are used to post result codes to a case. There is a separate menu for each *range* of codes. Thus, there is a separate menu for the baseline events, for each of the follow-up interviews, as well as a menu to post pregnancy or participation termination events. This component is described in Section F.

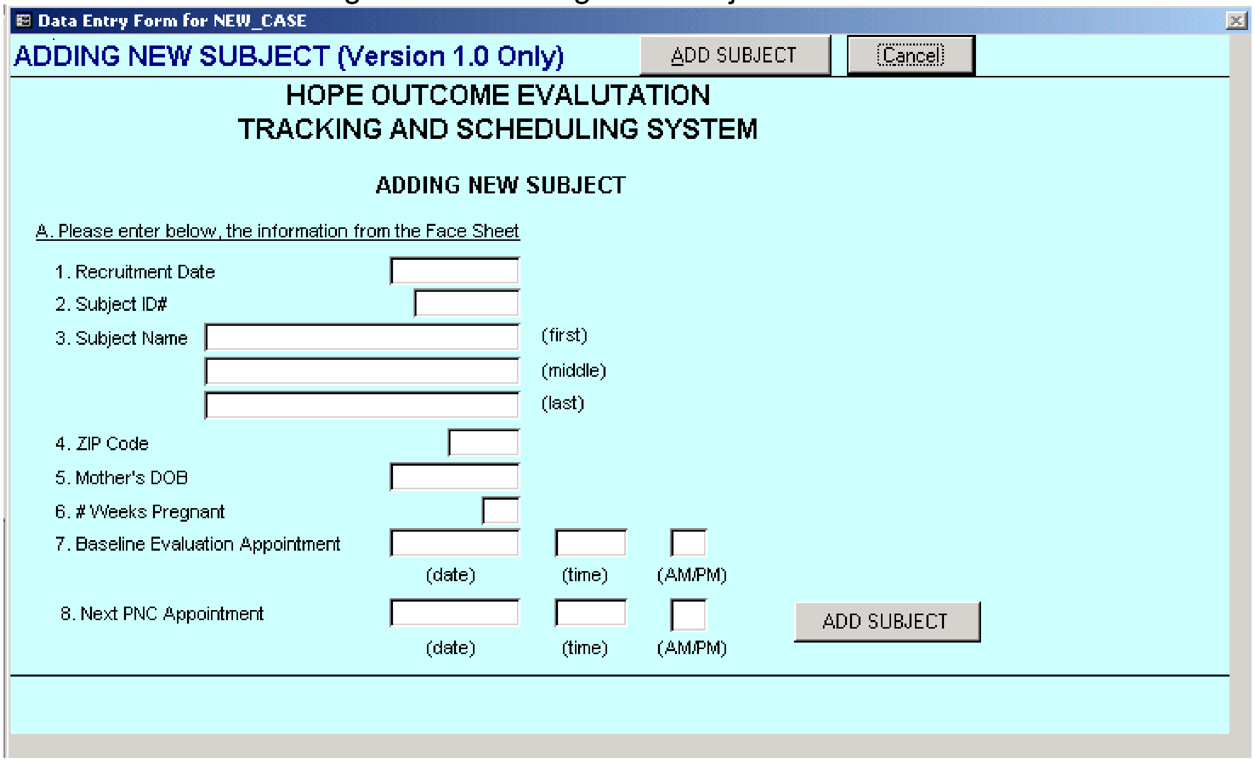
5. The *Interviewer Assignments* button is used to change the interviewer assignment for any given case. The interviewer is initially assigned when the case is added to the system, but can be changed at any time. The assigned interviewer appears on the reports generated from the System. This is described in more detail in Section G.

6. The *SuperUser* button is used by RTI staff to perform special operations. You will not need to use this component.

C. Main Menu Function: Adding a New Subject

On a daily basis, the Pregnancy Advisor Assistants at each clinic will be faxing you Face Sheets for all women who were recruited that day. You are responsible for adding these participants to the DMS. To do so, click the *Add New Subject* button on the Main Menu. A data entry form will appear, as shown in Figure VI.4. This form is used to initiate a new case in the tracking system by keying the minimal set of necessary information. The information you enter will come directly from the Face Sheet. All of the fields on the form must be filled in except for the *Middle Name, Zip Code,* and the *Baseline Evaluation Appointment* information (these fields should be filled in if this information is available).

Figure VI.4: Adding New Subject Screen



There are several things that you will need to keep in mind as you are adding a new subject to the system:

1. The "S" in the *Subject ID* will be filled in for you once you begin to type.

2. You should enter the date fields by typing the date in the MMDDYYYY format. Slashes and/or dashes are not entered. The computer will automatically display these after the date has been entered.

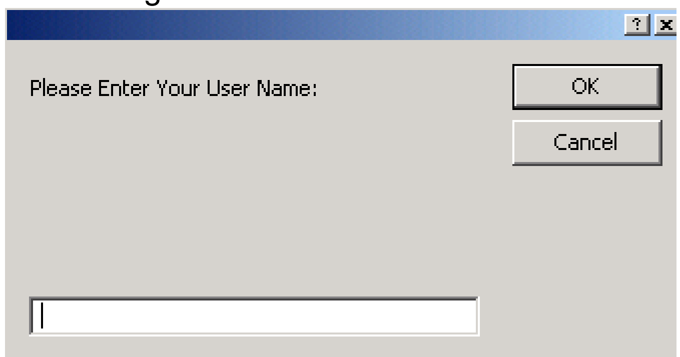
3. Similarly, the time is entered in the HHMM format. Do not enter any colons or other symbols. The AM/PM field can be filled in by entering the characters *am* or *pm*, or you can key '0' ENTER for AM and '1' ENTER for PM.

4. The date of the *Next PNC Appointment* is not allowed to be more than 6 weeks in the future. If the date that you enter is in the past, or more than 42 days in the future, an error message will be displayed.

5. As you fill a data entry field, the cursor will automatically move to the next field. For some fields where not all available space is utilized, such as the persons' name, you can use either the ENTER or TAB key to move to the next field.

After you fill in the last data entry field, the cursor will move to the *ADD SUBJECT* button. At this time, you will be asked, "Are you Ready to Add This Subject?" If all of the information is correct, click the "Yes" button (or simply Press Enter), and the values that you have keyed will be checked. If the System detects any errors, it will let you know at this time. Once an acceptable record has been keyed, the System will ask you two more questions. The first value queried is your user name, as shown in Figure VI.5 below:

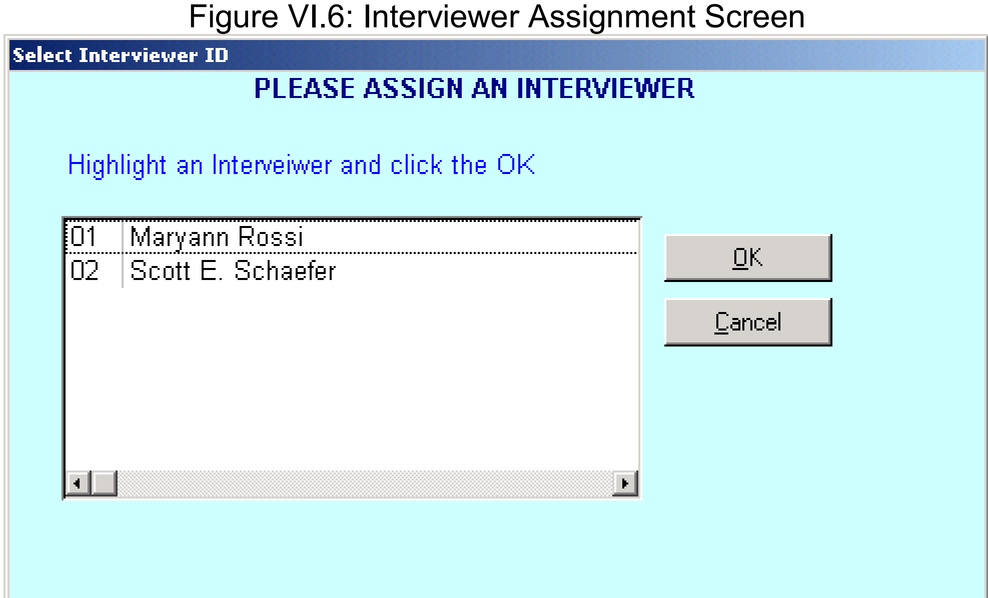
Figure VI.5: User Name Screen



Enter the user name that your supervisor assigned to you. The system will remember your user name for 30 minutes, so if you are entering data for more than one participant, you will not have to enter your user name again until that time has elapsed. However, if multiple people are using the system within a short time frame, it is advisable for each person to completely exit the system when they are finished so that the next person will have to enter her user name as well.

The second question that you will be asked when you add a new subject is the interviewer to assign to the case. Select the desired interviewer, as assigned by your supervisor, and click the *OK* button (you can also simply press the ENTER key).

Figure VI.6: Interviewer Assignment Screen



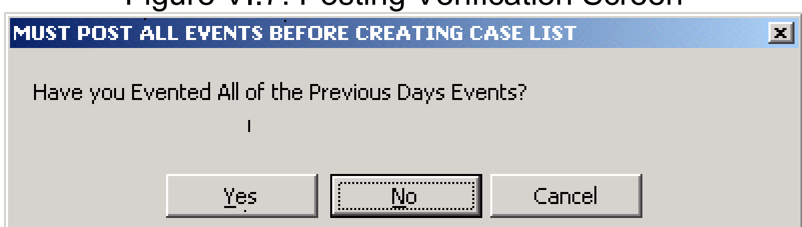
Once these values are entered, the participant will be added to the DMS and the form cleared. You can enter another new case, or click the *Cancel* button to return to the Main Menu.

D. Main Menu Function: Printing Active Case Lists

As described previously, the *Print Active Case Lists* button is used to create a printout of the subjects that are currently scheduled for any of the four evaluation interviews. This option should be executed ONLY once a day, in the morning, to obtain a list of the required telephone work for the day. Do not select this option unless specifically directed to do so by your supervisor.

Before any lists are printed, the records in the System are searched to determine if any participants are moving into or out of an evaluation window. For example, it will determine if a participant is currently at the appropriate "window of time," or gestational age, for a prenatal follow up interview. It will open interview windows for women who are currently eligible for a particular interview, and close windows for those women who are past the appropriate gestational age. When an evaluation window is automatically closed in this manner, it is no longer possible to post a result code for that evaluation. Therefore, it is **very important** that you post all result codes from the previous day or weekend **before** you run this option. To stress this importance, before the System begins searching the records and opening or closing windows, it will verify that you have entered all result codes into the System, as shown in Figure VI.7:

Figure VI.7: Posting Verification Screen



If you have not yet entered all interview results into the System, select "No" and complete the data entry. Otherwise, select "Yes," and the Active Case Lists will be printed automatically. Four different reports will be printed, as described in Chapter IV:

1. A report showing the number of participants scheduled for each evaluation interview and the number of windows that have just opened and closed.
2. A list of active participants (i.e., those women who are currently eligible for an evaluation interview) with appointments today.
3. A list of active participants with appointments in the future.
4. A list of active participants with no scheduled appointments. These are the participants for whom interviews must be scheduled.

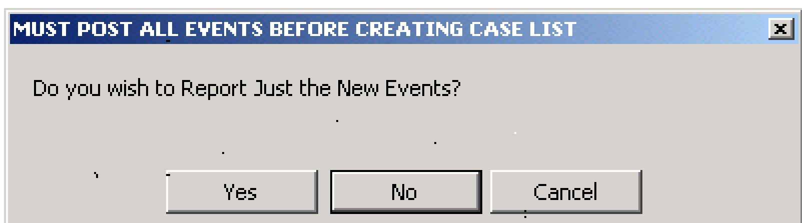
E. Main Menu Function: Summary Reports

This button on the main menu allows you to generate reports that summarize the interviewing activities that have taken place. The following reports can be generated, and can either be viewed on the screen or sent to the printer:

1. *Current Participant List*. This report, shown in Exhibit VI.2, provides a summary of all current Project HOPE participants. Women will be added to this list when you have input their information into the DMS, and will remain on it until their participation is terminated, or until they complete the postpartum evaluation interview. This report will include women with pending interviews, as well as those women who are currently between interview windows. This report may be sorted either by Subject ID or by the subject's last name.

2. *Completed Evaluations*. This report, shown in Exhibit VI.3, lists all completed interviews for each interviewer. The user may specify the reporting dates, and the report can be sorted either by Subject ID or by completion date. This report will be used mainly for supervision and quality control.

3. *List of Events to Report to the Clinics*. At the end of each day, you must fax to each clinic a list of participants for whom interviews have been finalized (either complete or incomplete), whose windows have been extended, whose pregnancy has ended, or who have terminated their participation. The DMS will generate a list of all such participants, sorted by clinic. To do so, select this report from the list. The System will ask you whether you wish to report just the new events, as shown below:



If you answer "Yes" to this question, the DMS will generate a report containing all activities that have not been reported before, regardless of the day that they were completed. Since these reports should be printed and faxed on a daily basis, the new events will likely be all events that occurred that day. Note that once you print this list, all of the events will be marked as having been "reported" and will not appear on future new event lists.

If you answer "No" to this question, you will be asked to enter a reporting date. The system will generate a list of all the events that occurred on that date only.

Note that the events for each clinic will be reported on a separate page so that you may easily fax to each clinic only the information that is applicable to them. This report will be sent automatically to the printer and will not appear on the screen. A sample report is shown in Exhibit VI.4.

4. *Identification Labels*. This option allows you to print a sheet of identification labels for any participant. You will enter the Subject ID number of the participant for whom you require labels, and the System will generate labels to be printed. Remember to insert a blank sheet of labels into the printer before selecting this option.

Exhibit VI.1: Current Participant List

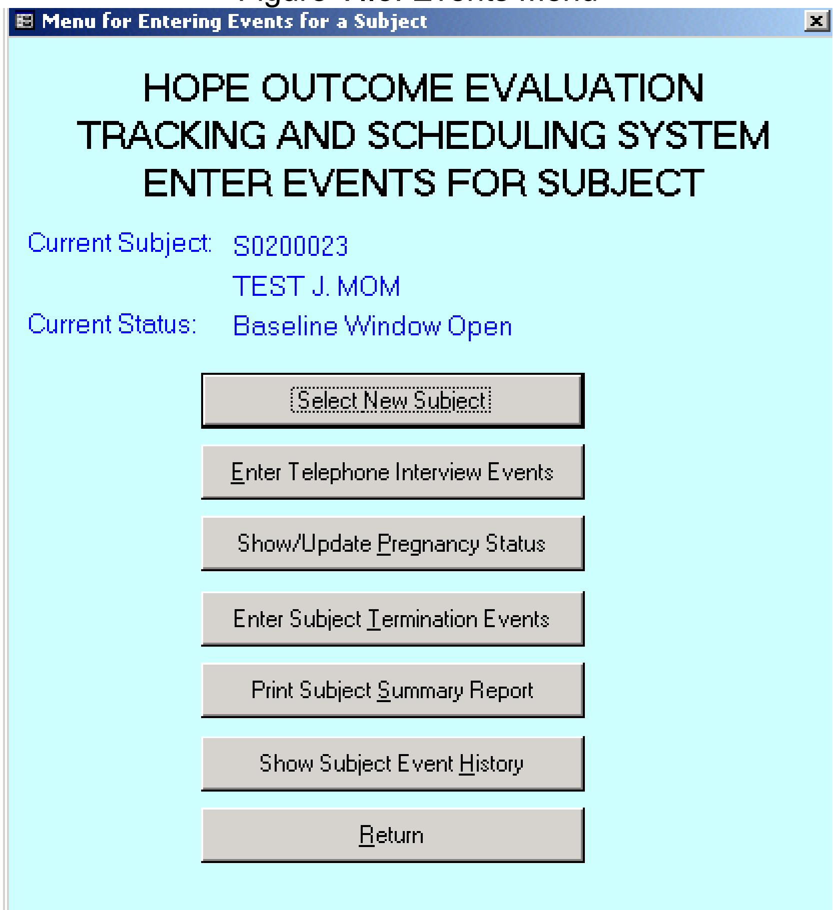
Exhibit VI.2: Completed Interviews

Exhibit VI.3: List Events to Report to the Clinics

F. Main Menu Function: Entering Events for a Subject

In the main menu, when you click on the button *Enter Events for Subject*, a sub-menu will appear that displays the types of events for which you may post a result code. This is the Events Menu, as shown in Figure VI.8:

Figure VI.8: Events Menu

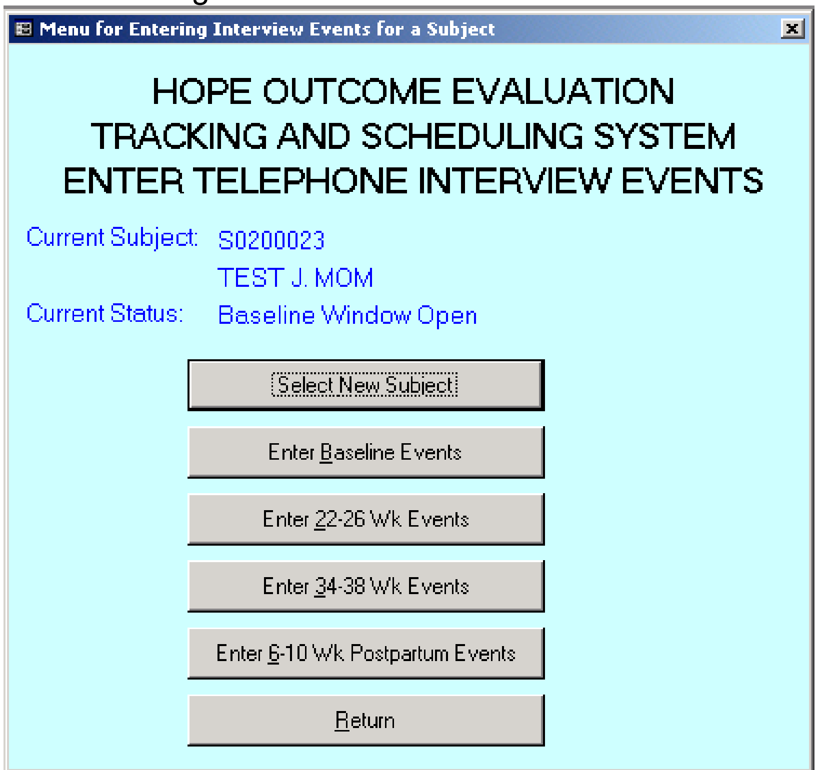


The various buttons on this menu allow you to update and manage different aspects of a participant's record. The function of each button on the Events Menu is described below.

1. *Select New Subject.* As you can see from Figure VI.8, the Current Subject field at the top of this menu will tell you if there is a *current case* selected. In this example, the participant is Test J. Mom. If there is no *current case*, or to select a new case, you should click on the *Select New Subject* button. A new screen will appear, like that shown in Figure VI.2, which asks you to enter the Subject ID for the appropriate participant. Once a subject is made the *current case* in this manner, result codes can be posted to that case.

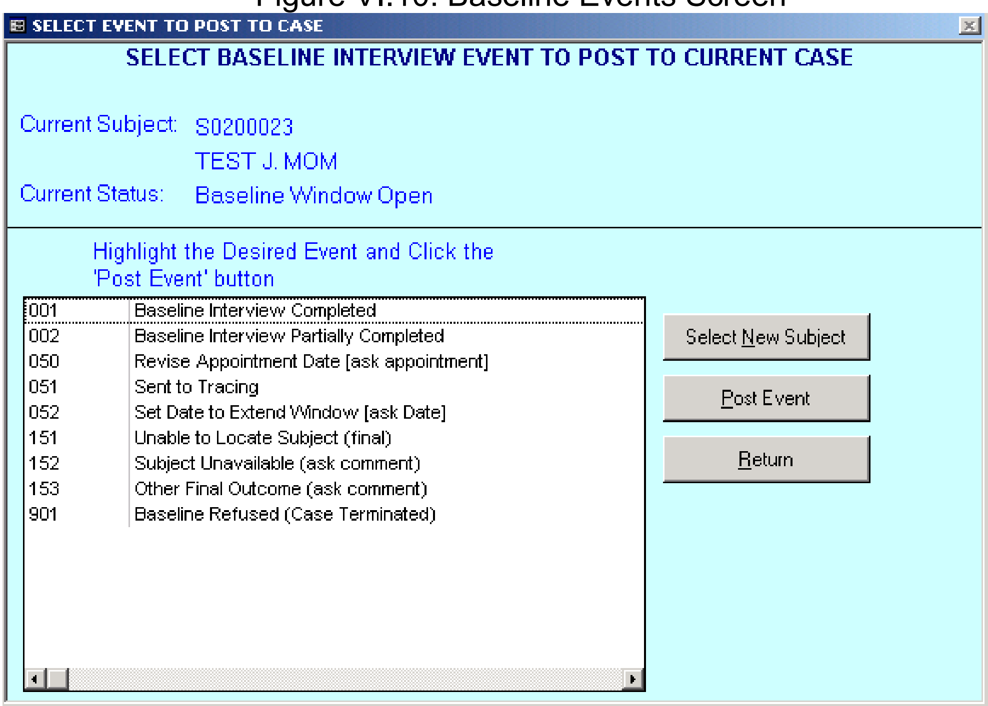
2. *Enter Telephone Interview Events*. Clicking this button will allow you to enter result codes for each of the four evaluation interviews. Another menu will appear, as shown in Figure VI.9, which allows you to select the specific interview for which you need to post a result. This is the Interview Menu.

Figure VI.9: Interview Menu



To display a list of result codes for each of these activities, click the button for the desired interview. The applicable result codes, as discussed in Chapter IV, will be displayed. For example, when the *Enter Baseline Events* button is clicked, the following form appears:

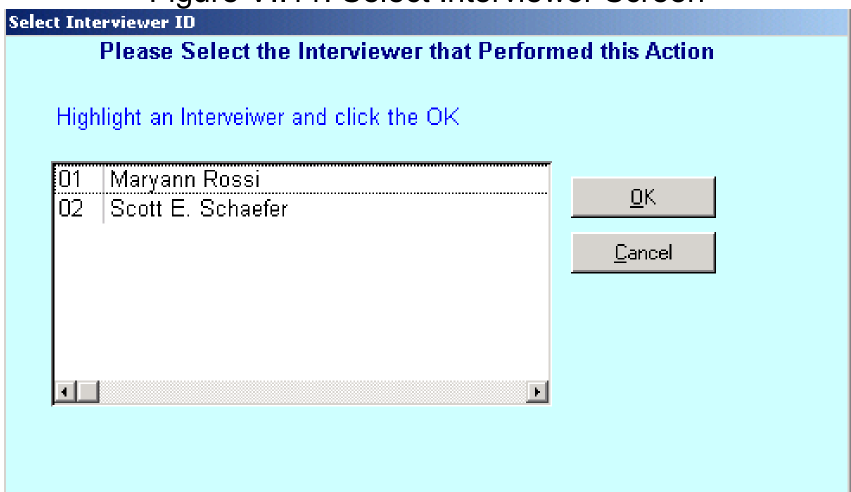
Figure VI.10: Baseline Events Screen



You can post a result code to the *current case* by clicking the desired event code and then clicking on the *post event* button. When you do this, you may be queried for your user name. If this happens, enter the name assigned to you by your supervisor.

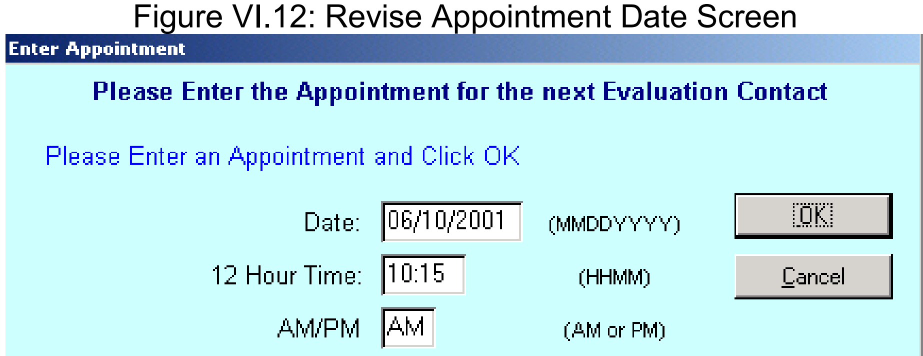
When a result code is selected that indicates that an interview activity has taken place (most of the result codes qualify), you will be asked to select the interviewer that performed the activity, as shown in Figure VI.11. To do so, select the desired interviewer from the list and then click the *OK* button (or press ENTER). Note that this is very similar to the screen in which an interviewer was initially assigned to the participant.

Figure VI.11: Select Interviewer Screen



If you select the event, "Revise Appointment Date," you will be asked to enter the appointment for the next evaluation contact, as shown in Figure VI.12. You should enter the data exactly as you do when you are adding a new subject. That is, the date should be entered in MMDDYYYY format without slashes, and the time entered in HHMM format.

Figure VI.12: Revise Appointment Date Screen



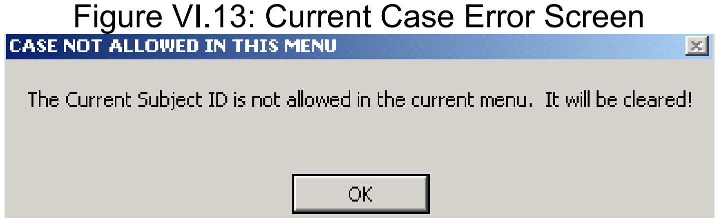
A similar form that only asks for a date value appears when the "Set Date to Extend Window" event is posted. This date is used to force the evaluation window to stay open beyond the time when it normally would close. An appointment that is beyond the window closing date will also extend the window to that date.

Once the event posting process is completed, the *current case* is cleared so that you can select a new case to event for that interview activity. If you are not posting any more results for the selected interview, you can also use the *Return* button to go back to the Interview Menu.

The event codes and procedures for the other evaluation interviews are identical to that shown for the baseline and are accessed by clicking the appropriate button. When a *current case* is selected, the current status of the case is displayed at the top of the menu so that you can easily see which set of evaluation events, if any, are appropriate for the subject. Evaluation result codes can only be posted to a participant's record if that participant currently has an open window for that evaluation.

Note that if you have selected a *current case* that is not currently scheduled for the evaluation interview that you have chosen, you will receive an error message similar to that displayed in Figure VI.13. The *current case* will be cleared and you will be allowed to click the *Select New Subject* button to enter an appropriate Subject ID for this interview type. If you wish to post results for a different interview type, click the *Return* button to go back to the Interview Menu and select that interview (you will have to re-establish the *current case)*.

Figure VI.13: Current Case Error Screen



Note that the *Return* button on the Interview Menu will take you back to the Events Menu. You may then select other options from this menu, for which description continues below.

3. *Show/Update Pregnancy Status.* This button on the Events Menu allows you to change the pregnancy status of a participant. When you click this button, you will see a screen that displays the pregnancy status of the *current case*, as shown in Figure VI.14.

   As before, use the *Select New Subject* button to change the *current case*, as displayed at the top of the form. You may also use the *Return* button to take you back to the Events Menu. If the subject is shown to be currently pregnant, and you wish to change this status to indicate that her pregnancy has ended, select the *Enter Pregnancy Termination Events* button. You will see the pregnancy termination screen, as shown in Figure VI.15.

   To change a participant's pregnancy status, select the appropriate pregnancy result and then click the *Post Event* button. If, during the course of an interview attempt, you discover that the woman is no longer pregnant and that the window for the postpartum interview is currently open (the woman is 6 to 10 weeks postpartum), you should conduct the interview.

Figure VI.14: Pregnancy Status Screen

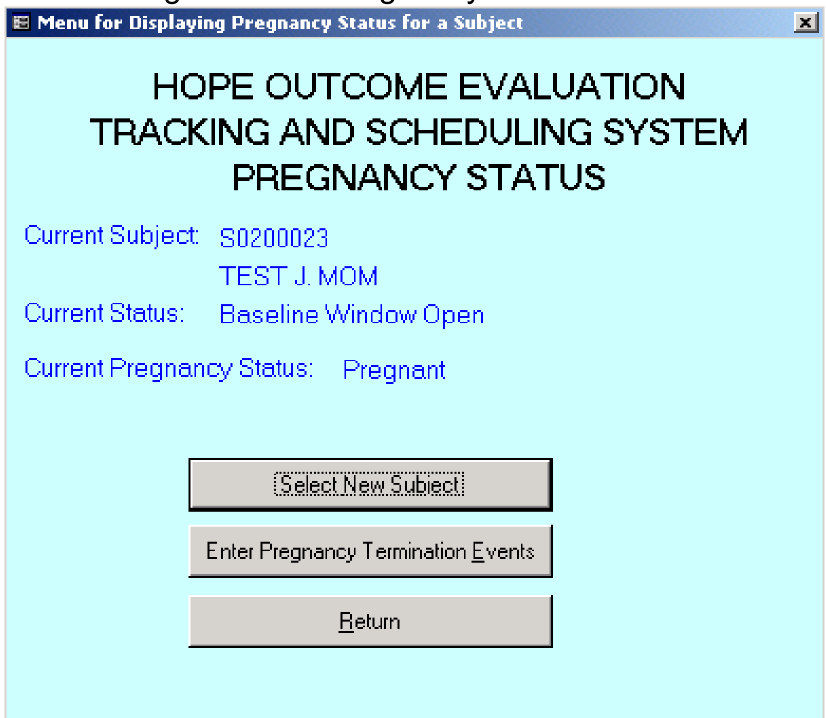
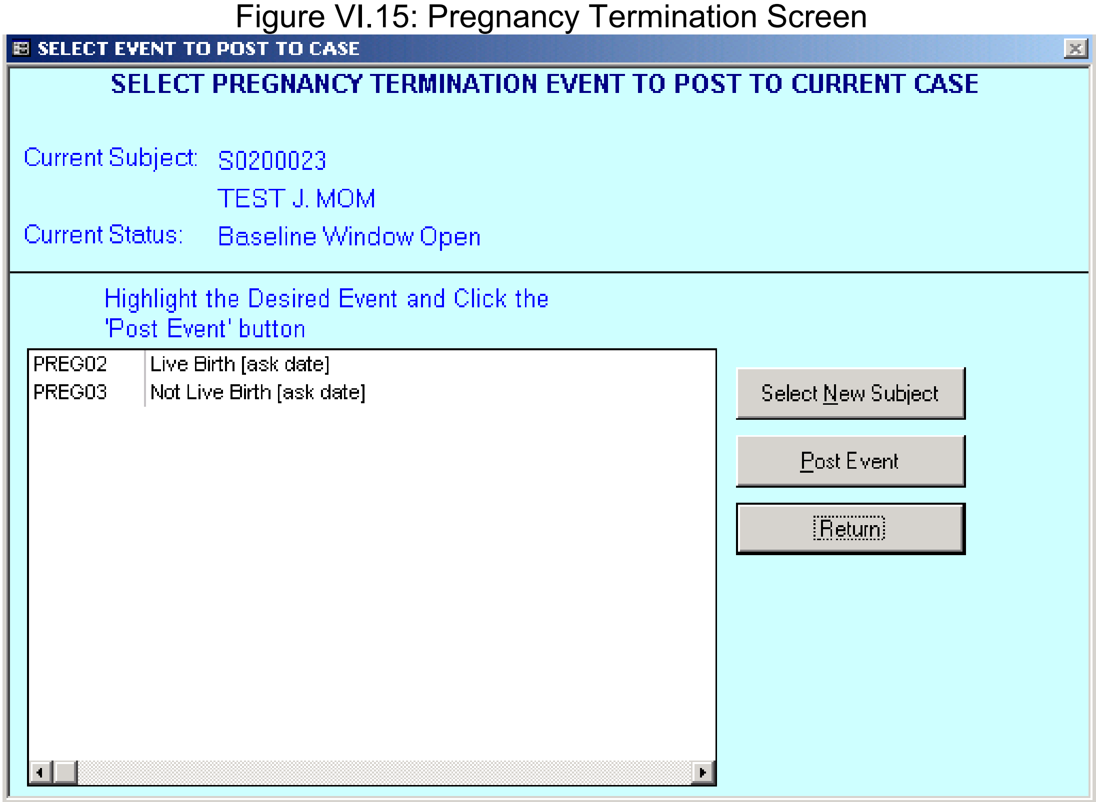
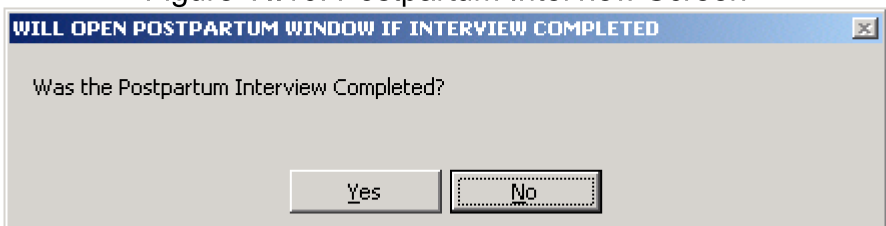


Figure VI.15: Pregnancy Termination Screen



When the pregnancy termination event from the menu above is posted to the case, you will be asked the date that the pregnancy ended and then asked the following question:

Figure VI.16: Postpartum Interview Screen

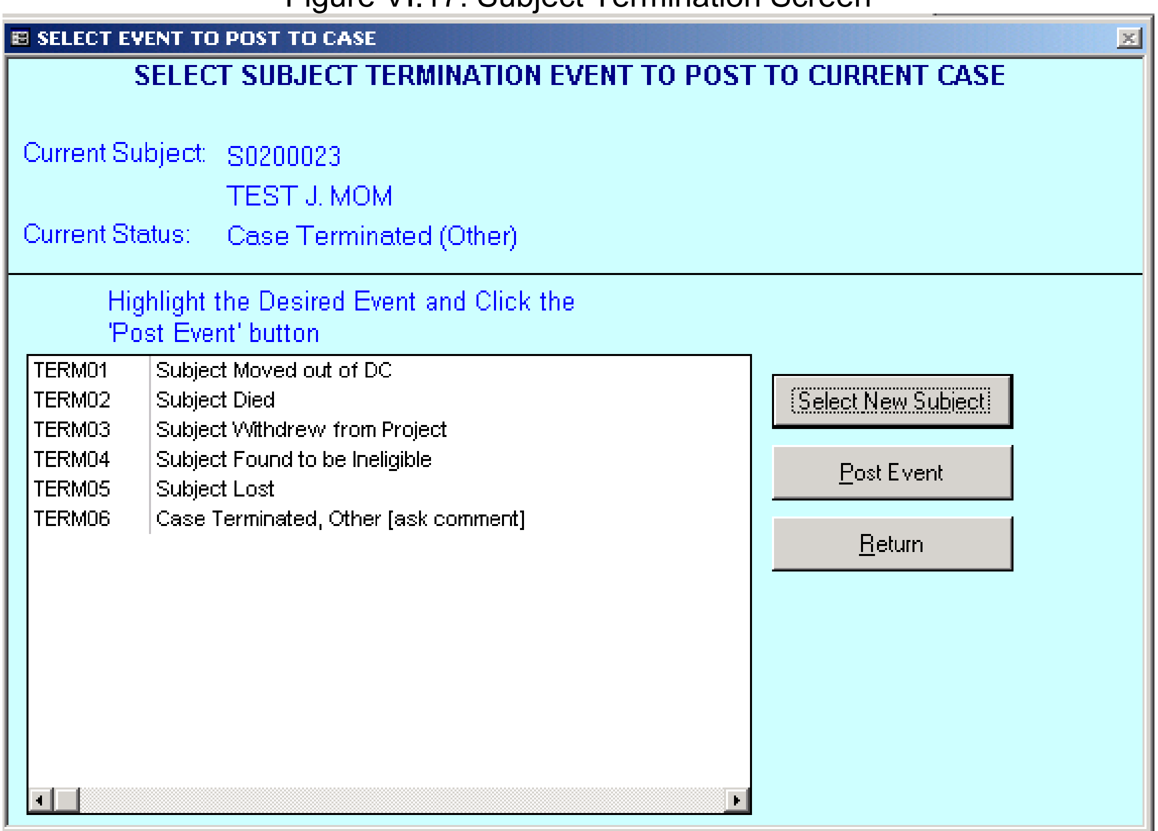


If you answer Yes to this question by clicking the *Yes* button, the postpartum interview window will be opened so you will be able to enter the result of that interview right away. If you indicate that the interview was not conducted, you will have to wait for the postpartum window to open in the usual way, when the woman reaches 6 weeks postpartum.

Once a pregnancy status change is posted, you can either select a new participant and change her pregnancy status, or use the *Return* button to go back to the previous screen.

4. *Enter Subject Termination Events*. You will use this button on the Events Menu if you learn that a woman is no longer participating in Project HOPE. This component allows you to enter the reason for termination. When you click on it, you will see the following form:

Figure VI.17: Subject Termination Screen



You post one of these events by clicking the desired event and then clicking on the *post event* button. Once one of these events is posted to a participant's record, the participant is terminated in the DMS and no further activity can be posted to the record. Again, use the *Select New Subject* button to enter termination events for another subject, or the *Return* button to go back to the Events Menu.

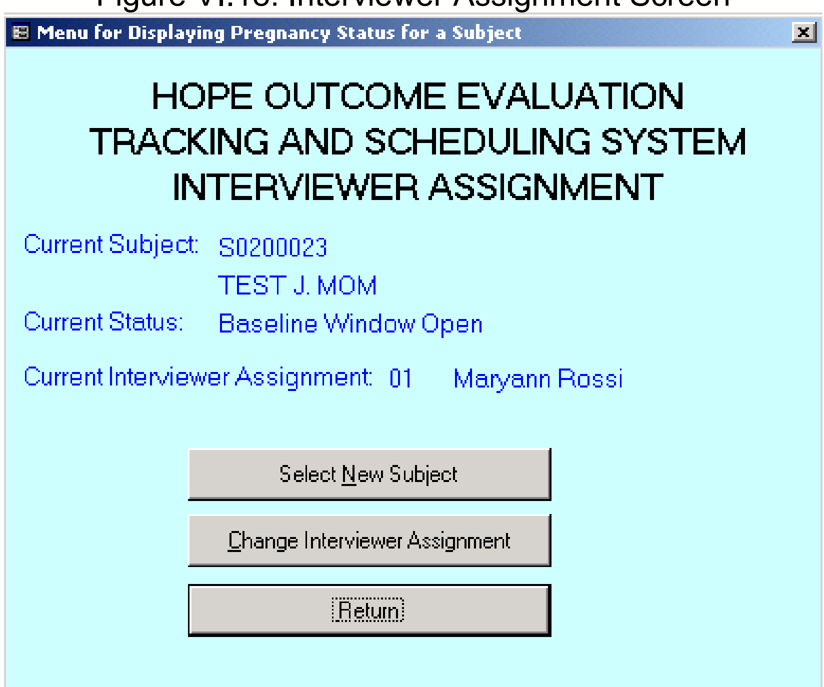
5. *Subject Summary Report.* This button on the Events Menu allows you to **print** a summary report for any Project HOPE participant. This report lists the current status of the subject and the results of each of the evaluation interviews. When you select this option, the report for the current case is automatically sent to the printer. If you wish to print additional summaries, use the *Select New Subject* button on the Events Menu to change the *current case*.

6. *Subject Event History.* This button on the Events Menu allows you to **view**, on the computer screen, all events that have been posted to a participant's record. It includes events that you have posted, as well as information that the System has updated automatically. Each event listed will include the result code, description, interviewer, and comment, as well as the date and time posted. It provides a more thorough description of the event history than does the Subject Summary Report.

G. Main Menu Function: Interviewer Assignments

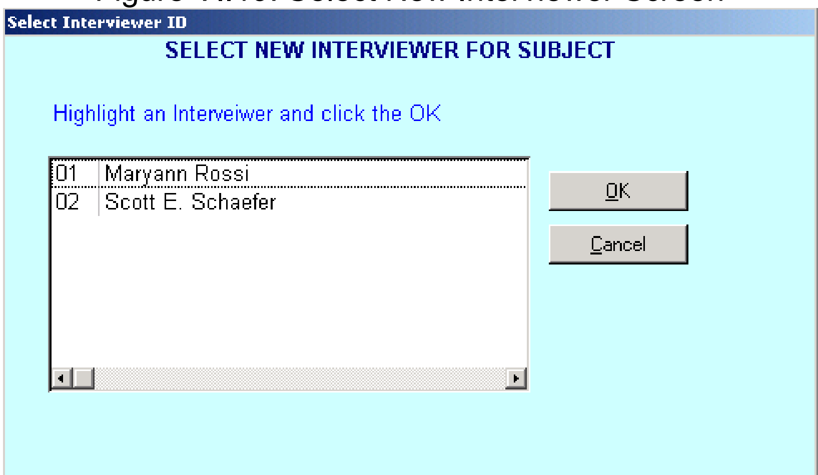
This button on the Main Menu allows you to display the interviewer assigned to any participant, and to change the interviewer assignment if necessary. You should only change an interviewer assignment if directed to do so by your supervisor. When you click this button, the following screen will appear:

Figure VI.18: Interviewer Assignment Screen



As with all other screens, the *Select New Subject* button will allow you to change the *current case*, and the *Return* button will take you back to the Main Menu. When the *Change Interviewer Assignment* button is clicked, you will see a form that asks you to select a new interviewer for the subject, as shown in Figure VI.19:

Figure VI.19: Select New Interviewer Screen



To change the interviewer assigned to a participant, click the appropriate interviewer's name from the list and then click the *OK* button. To leave the interviewer unchanged, click the *Cancel* button, and you will return to the previous screen. If you do change the interviewer, you will be requested to enter a comment. Please enter the reason for the interviewer change.